



July 6, 2012

**VIA ECF**

Hon. Tonianne J. Bongiovanni, U.S.M.J.  
U.S. District Court for the District of New Jersey  
Clarkson S. Fisher Building & U.S. Courthouse  
402 East State Street  
Trenton, New Jersey 08608

**Re: *Takeda Pharmaceutical Company Limited, et al. v. Mylan Inc. et al.*  
Civil Action No. 3:11-cv-02506-JAP-TJB**

John E. Flaherty  
Partner  
T. 973.639.7903  
F. 973.297.3971  
jflaherty@mccarter.com

McCarter & English, LLP  
Four Gateway Center  
100 Mulberry Street  
P.O. Box 652  
Newark, NJ 07102  
T. 973.622.4444  
F. 973.624.7070  
www.mccarter.com

BOSTON

HARTFORD

NEW YORK

NEWARK

PHILADELPHIA

STAMFORD

WILMINGTON

Dear Judge Bongiovanni:

We, along with Hogan Lovells, represent Plaintiffs Takeda and Ethypharm<sup>1</sup> in this action. We write to seek an Order from this Court striking new arguments raised by Defendant Mylan Pharmaceuticals Inc. ("Mylan") for the first time in its responsive claim construction brief (D.I. 81) and supplemental expert declaration (D.I. 80). By improperly introducing new non-rebuttal arguments in its responsive brief, Mylan has effectively prevented Plaintiffs from responding to those arguments and severely prejudiced Plaintiffs.

For the first time in its responsive brief, Mylan advanced a claim construction for the '994 patent<sup>2</sup> term "enteric coating layer." In flagrant disregard of the disclosure requirements set forth in L. Pat. R. 4.2 and 4.3, Mylan never disclosed to Plaintiffs its newly proposed construction or any supporting evidence. (See, e.g., Joint Claim Construction Chart and Prehearing Statement (D.I. 59), which is silent as to Mylan's new construction and cites to no supporting intrinsic or extrinsic evidence.) And yet, the "local patent rules are created to further the goal of full, timely discovery and provide all parties with adequate notice and information with which to litigate their cases" to prevent "litigation by ambush." *APP Pharms. LLC v. Ameridose, LLC*, Civil Action No. 10-4109, 2011 WL 6325975, at \*1 (D.N.J. Dec. 6, 2011) (quotation omitted).

Mylan also articulated for the first time two new indefiniteness arguments as to the '632 patent<sup>3</sup> terms "permits to obtain reduced pH influence in the digestive tract" and "permits to obtain . . . reduced influence of viscosity." But it is Mylan's burden to prove, by clear and convincing evidence, that the claim terms are invalid for indefiniteness. It is not Plaintiffs' burden to prove the contrary. Mylan should

---

<sup>1</sup> "Plaintiffs" refers to Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals North America, Inc., Takeda Pharmaceuticals LLC, Takeda Pharmaceuticals America, Inc. (collectively, "Takeda"), and Ethypharm, S.A.

<sup>2</sup> United States Patent No. 6,328,994

<sup>3</sup> United States Patent No. 5,464,632

Hon. Tonianne J. Bongiovanni, U.S.M.J.  
July 6, 2012  
Page 2

have presented its indefiniteness arguments, at the minimum, in its opening brief. Likewise, Mylan argues for the first time that the '994 file history supports its proposed construction that the "enteric coating agent" and "sustained-release agent" must be separate and distinct.

Accordingly, Plaintiffs request that the Court strike the following new arguments by Mylan:

- Mylan's argument that "enteric coating layer" must be an admixture of an enteric coating agent and sustained-release agent (Def.'s Resp. Br. at 14-20) and supporting paragraphs and exhibits from the Supplemental Declaration of Dr. Russell J. Mumper ("Mumper Supp. Decl.") ¶¶35-44, 46-47; Exhibits 22-28;
- Mylan's indefiniteness argument regarding "permits to obtain reduced pH influence in the digestive tract" (Def.'s Resp. Br. at 26-28); Mumper Supp. Decl. ¶¶50-53;
- Mylan's indefiniteness argument regarding "permits to obtain . . . reduced influence of viscosity" (Def.'s Resp. Br. at 29-30); Mumper Supp. Decl. ¶¶50, 54-56; and
- Mylan's argument that the '994 file history purportedly supports that the "enteric coating agent" and "sustained-release agent" must have "separate and distinct" claim constructions (Def.'s Resp. Br. at 14); Mumper Supp. Decl. ¶¶32-34, 45; Exhibits 23-25.

*See Pall Corp. v. Cuno Inc.*, No. 03-CV-0092 (JS)(ETB), 2007 WL 2363019, \*1 n.1 (E.D.N.Y. Aug. 14, 2007) ("Any arguments raised for the first time in reply [claim construction] briefs or letters filed subsequent to the briefs will not be considered by this Court in rendering its decision."); *see also SPX Corp. v. Bartec USA, LLC*, No. 06-14888, 2008 WL 1749479, at \*1-4 (E.D. Mich. April 11, 2008) (finding the Court would have struck defendants' expert declaration, which was filed for the first time with their responsive claim construction brief and introduced new arguments, had the defendants not withdrawn the declaration themselves).

In the event that the Court decides to entertain Mylan's new arguments, Plaintiffs respectfully request that the Court level the playing field by permitting Plaintiffs to file a reply brief and supplemental expert declaration to rebut Mylan's new arguments. *Biovail Labs. Int'l SRL v. Cary Pharm. Inc.*, No. 09-605, 2010 WL 2132021, at \*2-3 (D. Del. May 26, 2010) (permitting plaintiff to file reply brief in response to new expert opinions introduced by defendants in answering claim construction papers to avoid prejudice to plaintiff); *Server Tech., Inc. v. Am. Power Conversion Corp.*, No. 06-00698, 2010 WL 1610395, at \*11 n.5 (D. Nev. April 19,

Hon. Tonianne J. Bongiovanni, U.S.M.J.  
July 6, 2012  
Page 3

2010) (granting defendant's motion for a surreply because plaintiff's reply claim construction brief raised new arguments to which defendant would otherwise be unable to respond).

For the Court's consideration, Plaintiffs' reply brief is attached hereto as Exhibit A and the Supplemental Declaration of Plaintiffs' expert, Dr. Stephen R. Byrn, is attached hereto as Exhibit B. The parties have met and conferred about Plaintiffs' submitted papers; although Plaintiffs requested Mylan's permission to file the attached papers, Mylan has not consented.

If the Court wishes to discuss the matters raised above in a teleconference, Plaintiffs are available at the Court's convenience.

Respectfully,

*s/John E. Flaherty*

John E. Flaherty

cc: Counsel of Record (via email)

Enclosures: Exhibits A-B